PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01106USC1

DECLARATION OF DR. MELVIN C. HUNT
UNDER 37 C.F.R. § 1.132

Mail Stop Amendment-Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment-Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

October 14, 2004
Date

Adrienne White

Dear Commissioner:

I, Dr. Melvin C. Hunt, declare that:

1. I hold a degree of B.S. in Animal Husbandry from Kansas State University in Manhattan, Kansas that was obtained in 1965. I hold a degree of M.S. in Animal Science from Kansas State University that was obtained in 1970. I hold a degree of Ph.D. in Food Science from the University of Missouri in Columbia, Missouri that was obtained in 1973.

2. From 1973-1975, I worked as a research chemist for Tennessee Eastman Company in Kingsport, Tennessee in the Health and Nutrition Division. Since 1975 to the present, I have held various professor positions at Kansas State University. Since 1991, I have been the Chair of

the Undergraduate Food Science Program at Kansas State University. I have taught several courses over the years at Kansas State University including: Meat Science, Processed Meat Operations, Advance Meat Science, Food Science Seminar, Topics in Meat Science and Muscle Biology, Meat Processing, and Livestock and Meat Evaluation. I have also performed numerous research projects in Meat Science and Muscle Biology including major emphasis on pigment chemistry, meat color, meat packaging, and factors effecting microbial soundness (shelf life) of meat. Thus, I have extensive experience in the processing of meat using modified atmosphere packaging.

3. My curriculum vita (attached as Exhibit A) details my professional affiliations related to animal science and meat science. I have served as President of the American Meat Science Association in 1995-1996, Chair of the Meat Science-Muscle Biology Section of National American Society of Animal Science ("ASAS"), Chair of the Midwestern ASAS Meat Science Section, and Chair of the Muscle Foods Division of the Institute of Food Technologists. I have been on the Editorial Board of the publication entitled "Journal of Muscle Foods." I also perform manuscript review for several peer-reviewed scientific publications including "Meat Science", "Journal of Muscle Foods", "Journal of Animal Science", and "Journal of Food Science."

4. I assisted in preparing some of the information included in Pactiv's GRAS notice (Exhibit B) that was filed with the Food and Drug Administration (FDA) on August 29, 2001. The specific modified atmosphere packaging (MAP) system that was presented in the GRAS notice was a meat packaging system containing 0.4 vol.% CO and was referred to in the notice as Pactiv's ActiveTech® meat packaging system. The ActiveTech® meat packaging system placed meat in polystyrene trays, which were covered with oxygen-permeable, polyvinyl chloride (PVC)

overwraps. The wrapped trays of meat were then placed in an outer barrier bag. Air was removed and replaced with a blend of 0.4 vol.% CO, 30 vol.% carbon dioxide, and the balance being nitrogen.

5. I performed a series of tests on the effects of the ActiveTech® meat packaging system with CO on fresh meat color, color stability, and shelf life. The conclusions reached for the ActiveTech® meat packaging system with CO were: (a) the color of Pactiv's ActiveTech® meat packaging system using CO resulted in products that were equally red to products packaged with traditional oxygen permeable overwrap; (b) color deterioration of meat during simulated retail display in Pactiv's ActiveTech® meat packaging system using CO compared well to products packaged with traditional oxygen permeable overwrap; (c) bacterial growth was neither encouraged nor suppressed by adding CO to Pactiv's ActiveTech® meat packaging system; and (d) CO in the ActiveTech® meat packaging system neither masked spoilage, nor extended color life beyond the point of microbial soundness. I further concluded that Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO might be eligible for GRAS status.

6. The results of the testing were surprising to me because it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red. This is believed to be the reason on why CO had not been allowed to be used with fresh meat in the United States for many years. Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO, however, did not fix the color of the meat pigment to red. Rather, the meat pigment turned brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap). This was a novel result and was not at all obvious due to the current and long standing thought that meat

exposed to CO would develop a color that would mask spoilage. In other words, the pigment of the meat when exposed to CO would produce an extremely stable form of the pigment, but this did not happen in the Pactiv Active Tech® system.

7. I also believe that the surprising results obtained in the testing of the ActiveTech® meat packaging system using 0.4 vol.% CO would be equally applicable to other low oxygen environment meat packaging systems having (a) a first layer being a substantially permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture containing 0.4 vol.% CO.

8. An example of a low oxygen environment meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a "peelable" system. The peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. The first layer is located closest to the meat, while the second layer is located farthest from the meat. The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the permeable first layer.

9. It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap).

10. Prior to Pactiv's Active Tech® system using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is

exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product. Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations.

11. Systems such as (a) Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO or (b) those systems having (i) a first layer being a substantially permeable layer, (ii) a second layer being a substantially impermeable layer, and (iii) a gas mixture containing 0.4 vol.% CO such as the above-described peelable system are new and novel approaches that address these technological needs.

12. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Oct 6, 2004

Melvin C Hunt

Dr. Melvin C. Hunt

MELVIN C. HUNT

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PERSONAL DATA:
Born: February 10, 1942
Married: Rae Jean Opie, August 20, 1965; Daughters: Paige and Holly

EDUCATION:
B.S. 1965 Animal Husbandry, Kansas State University, Manhattan, KS
M.S. 1970 Animal Science, Kansas State University, Manhattan, KS
Ph.D. 1973 Food Science, University of Missouri, Columbia, MO

PROFESSIONAL EXPERIENCE:
1991- Chair, Undergraduate Food Science Program
1984- Professor, Kansas State University: 50% Teaching - 50% Research
1978-84 Associate Professor, Kansas State University
1975-78 Assistant Professor, Kansas State University
1973-75 Research Chemist, Tennessee Eastman Company
1968-73 Grad Research Assistant, Kansas State and University of Missouri
1966-68 Taught high school chemistry and biology, Kinsley, KS

PROFESSIONAL AFFILIATIONS:

American Meat Science Association:
- President, 1995-96; Past-President, 1996-97
- Director and Executive Board, 1989-91
- Chair 1991 Reciprocal Meat Conference
- Parliamentarian
- Chair or member of numerous committees including:
  Meat Color Guidelines, AMSA Teaching Award, Undergraduate Travel Award, Grad Student Poster Competition, Teaching Display, Resolutions, Meat Tenderness, Biochemistry-Biophysics, Packaging, Meat Color, Growth and Development, Reciprocation, Long Range Planning, Sustaining Membership, Endowment, and Research Priorities.

American Society of Animal Science:
- Chair and Chair-elect, Meat Science-Muscle Biology Section of National ASAS Meeting
- Chair, Midwestern ASAS Meat Science Section
- Editorial Board Journal Animal Science
- Teaching Award Committee, Midwestern ASAS Section

Institute of Food Technologists:
- Chair and Chair-elect of Muscle Foods Division, 1992-94
- Director of Muscle Foods Division
- Chair of Muscle Foods Nominating Committee
- Committee for two National Muscle Foods Symposia
- Journal of Food Science, Manuscript Review

CAST: Contributing member

Journal of Muscle Foods: Editorial Board

HONORARY AFFILIATIONS:

Phi Kappa Phi, Sigma Xi, Phi Tau Sigma, Gamma Sigma Delta, Alpha Zeta

HONORS:

- College of Agriculture Outstanding Faculty Award 1979
- College of Agriculture Outstanding Faculty Award 1982
- College of Agriculture Outstanding Faculty Award 1988
- College of Agriculture Outstanding Faculty Award 1998
- College of Agriculture Outstanding Academic Advisor 1983
- University Selection for Parents' Day Lecture 1979
- Outstanding Lecturer Award, ITAL, Campinas, Brazil 1981
- Honorary State Farmer Degree 1985
- Distinguished Teaching Award, Gamma Sigma Delta 1989
- Selected Instructor, National Food Science Satellite Program 1990
- Certificate of Meritorious Service, Kansas Ag Teachers Association 1992
- CASE Professor of the year, Kansas winner of national competition 1992
- Outstanding Advising Award, Gamma Sigma Delta 1994
- Distinguished Teaching Award, American Meat Science Association 1994
- Outstanding Food Scientist, Phi Tau Sigma 1996
- Outstanding KSU Instructor & Advisor Award, Mortar Board 1997
- Signal Service Award, American Meat Science Association 1997
- USDA Food & Agriculture Science Excellence in Teaching Award, 2000

DEPARTMENT, COLLEGE OF AG, AND UNIVERSITY ACTIVITIES:

- Faculty Advisor: Block and Bridle, 6 years
- Faculty Advisor: Food Science Club, 3 years
- Faculty Advisor: Animal Science Grad Student Association, 16 years
- Faculty Advisor: Ag Student Council, elected for 2 terms (4 years)
- Chair, Weber Hall Building/Renovation Project
- Chair, KSU Meat Science Faculty
- Coordinator of KSU Meat Research Labs
- ASI Graduate Student Selection Committee
- ASI Undergraduate Career Development Committee
- ASI Library Committee
- ASI Scholarship, Loans and Honors Committee
- Department Representative for Gamma Sigma Delta, 10 years
- Student Team Coordinator, ASI Quadrathalon Teams
- Agriculture Student of the Month Selection Committee
- Agriculture Faculty of the Semester Selection Committee
- College of Agriculture Course and Curriculum Committee, chair and member
- College of Agriculture Academic Standards Committee, chair and member
- College of Agriculture Commencement Committee
- University Faculty Senator, College of Agriculture, two terms (6 years)
- University Academic Affairs Committee
- University Coordinating Committee for United Way
- KAES NCR-131 Chair and Secretary: Food & Feed Safety in Animal Production
- Food Science Undergraduate and Graduate Steering Committees
- Chair, Non-Traditional Studies Advisory Committee
- Elected by peers to ASI Teaching Advisory Committee
- Chair, KSU Undergraduate Food Science Program: Coordinate all course & curriculum and policy matters, scholarship, internships, recruitment, and record keeping

INDUSTRY-EXTENSION ACTIVITIES:

- Numerous presentations at: MidWest Meat Processors Seminars, Kansas-Nebraska Curing and Sausage Short Courses, KSU Cattlemen's Day, KSU Swine Day
- Technical Assistance for: Tennessee Eastman Company, Ross Industries, Giant Food

Stores, Excel Corporation, IBP, Doskocil Companies, Tenneco Packaging, Farmland, National Beef, Cryovac, Buckhead Beef, Dupont, Kalsec, Wendy's, Greater Omaha Beef, Hormel

- State FFA Livestock Awards Selection Committee
- State FFA Star Farmer Selection Committee
- State FFA Public Speaking Contest Judge
- Kansas Jr. Livestock Carcass Contest Judge
- Kansas Meat Processor Cured Meat Show Judge
- Missouri Meat Processor Cured Meat Show Judge

TEACHING RESPONSIBILITIES:

Current Courses - KSU Campus:

- ASI 350 Meat Science. 3hr. Lecture-lab introductory meat science
  Enrollment: Since 1979, 2031 students; currently running at maximum seating of 72
- ASI 610 Processed Meat Operations. 2hr. 50% responsibility, value-added processing
  Enrollment: 6 to 12 undergraduate and graduate students; since 1988, 35 students
- ASI 930 Advanced Meat Science. 3hr. Team-taught, highest level meats course
  Enrollment: Varies from 6 to 15 graduate students
- GENAG 500 Food Science Seminar. 1hr. Seminar for graduating seniors
  Enrollment: Varies from 6 to 15 students

Current Courses - KSU Distance Learning Program:

- ASI 340 Principles of Meat Science. 2hr. Web-based course for Continuing Education
  Enrollment: Since 1987, over 680 students
- GENAG 500 Food Science Seminar. 1hr. Seminar series for Distance Learning majors
  Enrollment: 3 to 15 undergraduate students per year, Continuing Education
- GENAG 630 Food Science Problems. 1hr. Detailed written investigation of current topics
  Enrollment: 2 to 8 students per year through Continuing Education

Previously Taught Courses:

- Topics in Meat Science and Muscle Biology
- Meats Judging Team (at University of Missouri)
- Meat Processing
- Livestock and Meat Evaluation
- Animal Agriculture and Consumers

INTERNATIONAL COURSE ACTIVITIES:

- Meat Science and Technology Short Course for Latin America, Institute for Food Technology, Campinas, Brazil, 6 weeks, one of two international lecturers
- Meat Science Facilities, University of Monterrey, Monterrey, Mexico
- Lecturer for five KSU International Meat Science Courses, International Meat and Livestock Program, Kansas State University
- Sabbatical leave, fall 1992, visiting scientist to Norwegian Food Research Institute, As
- Have attended 8 International Congresses of Meat Science and Technology

ADVISING RESPONSIBILITIES:

- Undergraduate Advisees: average of 26 for the last 10 years
  - Graduate Students Supervised:
    - 12 Masters Students
    - 6 PhD Students
  - Graduate Student Committees:
    - 43 Masters
    - 20 PhD
  - Coordinate student-company relations for employment and internships for FSI

RESEARCH INTERESTS:

- Myoglobin chemistry and meat color, Methods of color measurement, Cooked meat color and food safety, Postmortem factors affecting meat quality, Collagen chemistry, Low-fat ground beef and processed meats; Six major company packaging projects funded since 1994 dealing with shelf life, color life, cold chain management, product palatability, and microbiology

PUBLIC AND COMMUNITY ACTIVITIES:

- Manhattan Optimist Club: committees for many youth activities
- Coach, Girls (16-18) ASA fast pitch softball traveling team
- Executive Committee, Riley County Extension Council
- Asst. Superintendent, sheep division, Riley County Fair
- Judge at Manhattan High School oratorical contest
- FarmHouse Fraternity, alumni board and committee work
- Snyder Award for Alumni Service, FarmHouse Fraternity
- Activities of First Presbyterian Church

Melvin C. Hunt
Professor
Department of Animal Sciences and Industry
Kansas State University

Refereed Journal Articles

Hunt, M.C., R.A. Smith, D.H. Kropf and H.J. Tuma. 1975. Factors affecting showcase color stability of frozen lamb in transparent film. J. Food Sci. 40:637.

Hunt, M.C. and H.B. Hedrick. 1977. Profile of fiber types and related properties of five bovine Muscles. J. Food Sci. 42:513.

Hunt, M.C. and H.B. Hedrick. 1977. Histochemical and histological characteristics of bovine muscle from four quality groups. J. Food Sci. 42:578.

Hunt, M.C. and H.B. Hedrick. 1977. Chemical, physical and sensory characteristics of bovine muscle from four quality groups. J. Food Sci. 42:716.

Thomas, J.D., D.M. Allen, M.C. Hunt and C.L. Kastner. 1977. Nutritional regimen, post-slaughter conditioning temperature, and vacuum packaging effects on beef carcass and retail cut bacteriology. J. Food Prot. 40:678.

Harrison, A.R., M.E. Smith, D.M. Allen, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1978. Nutritional regimen effects on quality and yield characteristics of beef. J. Anim. Sci. 47:383.

Loveday, H.D., M.E. Dikeman, M.C. Hunt and A.D. Dayton. 1978. Adipose tissue water related to bovine carcass composition. J. Anim. Sci. 47:606.

Smith, M.E., C.L. Kastner, M.C. Hunt, D.H. Kropf and D.M. Allen. 1979. Elevated conditioning temperature effects on carcasses from four nutritional regimens. J. Food Sci. 44:158.

Gutowski, G.H., M.C. Hunt, C.L. Kastner, D.H. Kropf and D.M. Allen. 1979. Vacuum aging, display, and level of nutrition effects on beef quality. J. Food Sci. 44:140.

Fung, D.Y.C., C.L. Kastner, M.C. Hunt, M.E. Dikeman and D.H. Kropf. 1980. Mesophilic and psychrotrophic populations on hot-boned and conventionally processed beef. J. Food Prot. 43:547.

Hayward, L.H., M.C. Hunt, C.L. Kastner and D.H. Kropf. 1980. Blade tenderization effects on beef longissimus sensory and Instron textural measurements. J. Food Sci. 45:925.

Harrison, A.R., D.H. Kropf, D.M. Allen, M.C. Hunt and C.L. Kastner. 1980. Relationships of spectrophotometric reflectance measurements to beef muscle visual color. J. Food Sci. 45:1052.

Burson, D.E., M.C. Hunt, D.M. Allen, C.L. Kastner and D.H. Kropf. 1980. Ration energy density and time on feed effects on beef longissimus palatability. J. Anim. Sci. 51:875.

Fung, D.Y.C., C.L. Kastner, C-Y. Lee, M.C. Hunt, M.E. Dikeman and D.H. Kropf. 1981. Initial chilling rate effects on bacterial growth of hot-boned beef. J. Food Prot. 44:539.

Wu, J.J., D.M. Allen, M.C. Hunt, C.L. Kastner and D.H. Kropf. 1981. Nutritional effects on beef collagen characteristics and palatability. J. Anim. Sci. 53:1256.

Hall, J.B. and M.C. Hunt. 1982. Collagen solubility of A-maturity bovine longissimus muscle as affected by nutritional regimen. J. Anim. Sci. 55:321.

Sleper, P.S., M.C. Hunt, D.H. Kropf, C.L. Kastner and M.E. Dikeman. 1983. Electrical stimulation effects on myoglobin properties of bovine longissimus muscle. J. Food Sci. 48:479.

Axe, J.E. Bowles, C.L. Kastner, M.E. Dikeman, M.C. Hunt, D.H. Kropf and G.A. Milliken. 1983. Effects of beef carcass electrical stimulation, hot boning, and aging on unfrozen and frozen longissimus dorsi and semimembranosus steaks. J. Food Sci. 48:332.

Lyon, M., C.L. Kastner, M.E. Dikeman, M.C. Hunt, D.H. Kropf and J.R. Schwenke. 1983. Effects of electrical stimulation, aging, and blade tenderization hot-boned beef psoas major and triceps brachii muscles. J. Food Sci. 48:131.

Greathouse, J.R., M.C. Hunt, M.E. Dikeman, L.R. Corah, C.L. Kastner and D.H. Kropf. 1983. Ralgro implanted bulls: performance, carcass characteristics, longissimus palatability and carcass electrical stimulation. J. Anim. Sci. 57:355.

Burson, D.B., M.C. Hunt, D.E. Schafer, D. Beckwith and J.R. Garrison. 1983. Effects of stunning method and time interval from stunning to exsanguination on blood splashing in pork. J. Anim. Sci. 57:918.

Shivas, S.D., D.H. Kropf, M.C. Hunt, C.L. Kastner, J.L.A. Kendall and A.D. Dayton. 1984. Effects of ascorbic acid on the display life of ground beef. J. Food Prot. 47:11.

Choi, Y.I., C.L. Kastner, M.E. Dikeman, M.C. Hunt and D.H. Kropf. 1984. Effects of electrical stimulation and hot boning on functional characteristics of preblended beef muscle in model systems. J. Food Sci. 49:867.

Claus, J.R., D.H. Kropf, M.C. Hunt, C.L. Kastner and M.E. Dikeman. 1984. Effects of beef carcass electrical stimulation and hot boning on muscle display color of polyvinylchloride packaged steaks. J. Food Sci. 49:1021.

Kropf, D.H., M.E. Dikeman, M.C. Hunt and H.R. Cross. 1984. Lighting type and intensity effects on beef carcass grade factors. J. Anim. Sci. 59:105.

Shivas, S.D., C.L. Kastner, M.E. Dikeman, M.C. Hunt and D.H. Kropf. 1985. Effects of electrical stimulation, hot boning, and chilling on bull semimembranosus muscle. J. Food Sci. 50:36.

Claus, J.R., D.H. Kropf, M.C. Hunt, C.L. Kastner and M.E. Dikeman. 1985. Effects of beef carcass electrical stimulation and hot boning on muscle display color of unfrozen vacuum packaged steaks. J. Food Sci. 50:881.

Dikeman, M.E., A.D. Dayton, M.C. Hunt, C.L. Kastner, J.B. Axe and H.J. Ilg. 1985. Conventional versus accelerated beef production with carcass electrical stimulation. J. Anim. Sci. 61:573.

Burson, D.E. and M.C. Hunt. 1986. Proportion of collagen types I and III in four bovine muscles differing in tenderness. J. Food Sci. 51:51.

Burson, D.E. and M.C. Hunt. 1986. Heat-induced changes in the proportion of types I and III collagen in bovine longissimus. Meat Sci. 17:153.

Burson, D.E., M.C. Hunt, J.A. Unruh and M.E. Dikeman. 1986. Proportion of types I and III collagen in longissimus collagen from bulls and steers. J. Anim. Sci. 63:453.

Flores, H.A., C.L. Kastner, D.H. Kropf and M.C. Hunt. 1986. Effects of blade tenderization and trimming of connective tissue on hot-boned, restructured, pre-cooked roast from cows. J. Food Sci. 51:1176.

Unruh, J.A., C.L. Kastner, D.H. Kropf, M.E. Dikeman and M.C. Hunt. 1986. Effects of low-voltage electrical stimulation during exsanguination on meat quality and display colour stability. Meat Sci. 18:281.

Allen, D.M., M.C. Hunt, A. Luchiari Filho, R.J. Danler and S.J. Goll. 1987. Effects of spray-chilling and carcass spacing on beef carcass cooler shrink and grade factors. J. Anim. Sci. 64:165.

McCormick, R.J., D.H. Kropf, G.R. Reeck, M.C. Hunt and C.L. Kastner. 1987. Effect of heating temperature and muscle type on porcine muscle extracts as determined by reverse phase high performance liquid chromatography. J. Food Sci. 52:1481.

Kluber, E.F. III, J.E. Minton, J.S. Stevenson, M.C. Hunt, D.L. Davis, T.A. Hoagland and J.L. Nelssen. 1988. Growth, carcass traits, boar odor and testicular and endocrine functions of male pigs fed a progesterogen, Altrenogest. J. Anim. Sci. 66:470.

Johnson, R.D., M.C. Hunt, D.M. Allen, C.L. Kastner, R.J. Danler and C.C. Schrock. 1988. Moisture uptake during washing and spray chilling of holstein and beef-type steer carcasses. J. Animal. Sci. 66:2180.

Claus, J.R., M.C. Hunt and C.L. Kastner. 1989. Effects of substituting added water for fat on the textural, sensory, and processing characteristics of bologna. J. Muscle Foods. 1:1.

Claus, J.R., M.C. Hunt, C.L. Kastner and D.H. Kropf. 1990. Low-fat, high-added water bologna: Effects of massaging, preblending, and time of addition of water and fat on the physical and sensory characteristics. J. Food Sci. 55:338.

Kenney, P.B. and M.C. Hunt. 1990. Effect of water and salt content on protein solubility and water retention of meat preblends. Meat Sci. 27:173.

Troyer, D.L., R.O. Oyster and M.C. Hunt. 1991. A combination histochemical stain for equine muscle. Anat. Histol. Embryol. 20:44.

Whipple, G., M. Koohmaraie, M.E. Dikeman, J.D. Crouse, M.C. Hunt and R.D. Klemm. 1990. Evaluation of attributes that affect longissimus muscle tenderness in *Bos Taurus* and *Bos Indicus* cattle. J. Anim. Sci. 68:2716.

Claus, J.R. and M.C. Hunt. 1991. Characteristics of low-fat, high-added water bologna formulated with textural modifying ingredients. J. Food Sci. 56:643.

Whipple, G., M.C. Hunt, R.D. Klemm, D.H. Kropf, R.D. Goodband, J.L. Nelssen, R.H. Hines and B.R. Schricker. 1992. Effects of porcine somatotropin and supplemental lysine on porcine muscle histochemistry. J. Muscle Foods. 3:217.

Troutt, E.S., M.C. Hunt, D.E. Johnson, J.R. Claus, C.L. Kastner, D.H. Kropf and S. Stroda. 1992. Chemical, physical, and sensory characterization of ground beef containing 5 to 30 percent fat. J. Food Sci. 57:25.

Troutt, E.S., M.C. Hunt, D.E. Johnson, C.L. Kastner and D.H.Kropf. 1992. Characteristics of low-fat ground beef containing texture-modifying ingredients. J. Food Sci. 57:19.

Goll, S.J., C.L. Kastner, M.C. Hunt and D.H. Kropf. 1992. Effects of glucose and internal cooking temperature on the characteristics of low fat, pre- and post-rigor restructured beef roasts. J. Food. Sci. 57:834.

Nold, R.A., J.A. Unruh, M.C. Hunt and C.W. Spaeth. 1992. Effects of implanting ram and wether lambs with zeranol at birth and weaning on palatability and muscle collagen characteristics. J. Anim. Sci. 70:2752.

Warren, K.E., M.C. Hunt, C.L. Marksberry, O. Sörheim, D.H. Kropf and M.J. Windisch. 1992. Modified-atmosphere packaging with carbon dioxide for bone-in pork loins. J. Muscle Foods. 3:283.

Nold, R.A., J.A. Unruh, C.W. Spaeth and M.C. Hunt. 1992. Effects of implanting ram and wether lambs with zeranol on pelt characteristics and removal. Sheep Res. J. 8:81.

Brester, G.W., P. Lhermite, B.K. Goodwin and M.C. Hunt. 1993. Quantifying the effects of new product development: The case of low-fat ground beef. J. Agric. & Resource Econ. 18:239.

Garcia Zepeda, C.M., C.L. Kastner, D.H. Kropf, M.C. Hunt, P.B. Kenney, J.R. Schwenke and D.S. Schleusener. 1993. Utilization of surimi-like products from pork with sex-odor in restructured, precooked pork roasts. J. Food Sci. 58:53.

Hague, M.A., K.E. Warren, M.C. Hunt, D.H. Kropf, C.L. Kastner, S.L. Stroda, and D.E. Johnson. 1994. Endpoint temperature, internal cooked color, and expressible juice color relationships in ground beef patties. J. Food Sci. 59:465-470.

Letelier, V., C.L. Kastner, P.B. Kenny, D.H. Kropf, M.C. Hunt, and C.M. Garcia Zepeda. 1995. Flaked sinew addition to low-fat cooked salami. J. Food Sci. 60:245-248.

Lavelle, C., M.C. Hunt, and D.H. Kropf. 1995. Display Life and Internal Cooked Color of Ground Beef from Vitamin E-Supplemented Steers. J. Food Sci. 60:1-4,6.

Sørheim, O., D.H. Kropf, M.C. Hunt, M.T. Karwoski, and K.E. Warren. 1996. Effects of modified gas atmosphere packaging on pork loin colour, display life and drip loss. Meat Sci. 43:203-212.

Campbell, R.E. and M.C. Hunt. 1996. Yields, chemical composition, and value of beef shank tissues obtained using Baader processing. J. Anim. Sci. 74:786-789.

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Educational Materials

Course Syllabi:

Distance Learning - Complete course, *PRINCIPLES OF MEAT SCIENCE* in "any-time or real-time" distance learning format via audiotapes, teleconferencing, on-line discussions involving collaborative learning, problem solving and critical thinking via the Internet.

In-Class - Laboratory Materials for *MEAT SCIENCE*, a series of 14 study guides for lab exercises
- Laboratory Materials for *PROCESSED MEAT OPERATIONS*

Other Materials and Activities:

USDA Grant: - Expanding Undergraduate Education for Food Industry Personnel via Technology. 1994-96 USDA Challenge Grant Program, $79,479

Web-based Course - Principles of Meat Science, KSU Division of Continuing Education

Color Guides
- Ground Beef Patty Cooked Color Guide
- Cured Meat Color Guide
- Cooked Pork Chop Color Guide
- Ground Pork Patty Cooked Color Guide

Science Series - Lesson Plans for: Promoting Ag Science for Secondary Schools
Developing New Meat Products
Color Chemistry in Meat Products
Meat Packaging Exercises for High School Students

Slides Series:
- Unraveling the Mystery of Premature Browning in Cooked Ground Beef Patties
- Doneness of Cooked Ground Beef
- Dynamics of Conversion of Myoglobin Forms
- Role of Pigment Layers in Influencing Surface Meat Color
- Spray Chilling of Carcasses
- Don't be Broken-Hearted because of High-fat in Ground Beef
- Commercial Sausage, Ham and Bacon Production
- Food Science at KSU
- ASI Quadrathlon - why I should participate
- Updated: Muscle-Bone Anatomy; Beef-Pork-Lamb Cut Identification

Video Tapes: - Beef Carcass Electrical Stimulation and Hot Boning (Edited with M. E. Dikeman)

Store Survey: - Out-of-class assignment for Analysis of Retail Meat Section of Grocery Stores

Diet Survey: - Out-of-class assignment for computerized class project of Nutritional Value of Muscle Foods in the student's diet

Current topic: Survey - Out-of-class assignment for critically analyzing printed literature on a variety of livestock and meat industry topics

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Contains Confidential Business Information

August 29, 2001

Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St, SW
Washington, DC 20204

Re: **NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT**

To the FDA:

This letter and its attachments contains the notification, pursuant to the Federal Food, Drug and Cosmetic Act and FDA's regulations, by Pactiv Corporation, 1900 West Field Court, Lake Forest, Illinois 60045, c/o attorney Eric F. Greenberg, 3500 Three First National Plaza, Chicago, Illinois 60602[1], for the General Recognition of Safety of carbon monoxide ("CO") at a level of 0.4% in a modified atmosphere system for packaging fresh meat.

[1] Attachment 1 contains Pactiv's authorization of undersigned counsel, as well as a Summary regarding Pactiv Corporation.

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As set forth more fully below and in the attachments to this document, Pactiv believes its intended use of CO is GRAS based on scientific procedures within the meaning of 21 U.S.C. Sec. 201(s) and FDA's implementing regulations in 21 CFR Sec. 170.30, and including FDA's proposed rule published on April 17, 1997 (62 FR 18937). FDA regulations provide that the scientific evidence available and reviewed for a GRAS determination is of the same quantity and quality as that required for a food additive approval, and that the scientific evidence of safety be generally known and accepted by qualified experts in the appropriate scientific and technical fields. 21 CFR Sec. 170.30(a).

I. Claim of Exemption

a. Name and address of the notifier.

Pactiv Corporation
1900 West Field Court
Lake Forest, Illinois 60045
c/o Eric F. Greenberg
Attorney at Law
3500 Three First National Plaza
Chicago, IL 60602

b. Common or usual name of the notified substance.

Carbon monoxide ("CO")

c. Conditions of use (foods, levels, purposes).

When used as described in this Notice, CO meeting appropriate purity specifications is a processing aid in packaging of fresh cuts of muscle meat and ground meat, as a component of a gas mixture utilized in a specific modified atmosphere packaging system. 21 CFR Sec. 170.3(o)(24). A technology utilizing 0.4% CO within a modified atmosphere packaging system will maintain wholesomeness, permit greater flexibility in distribution, and reduce shrinkage, all within a system that results in traditional product display to consumers. All elements of the system, excluding the CO, are already in use in the United States as part of a modified atmosphere meat packaging system called ActiveTech™. Notifier refers to the new system incorporating CO as "AT2001".

Summary

ActiveTech™ is a system that is designed to permit more extended storage of meats, but, as explained below, has no effects on retail display time or characteristics as compared with other modified atmosphere technologies currently in use. It employs materials that are either approved additives used consistently with their approvals, or GRAS substances. AT2001 adapts that system for additional storage scenarios. AT2001 serves to reduce the time needed for enzymatic reduction after modified

atmosphere packaging, and allows consistent display color of whole muscle meats. AT2001's advantages are in the resulting flexibility and consistency during storage and distribution.

The GRAS use of CO described in this Notice involves use as a component of the flush gas mixture used in replacement of ambient air in the packaging for distribution of refrigerated fresh red meat. The meats are in all instances fresh, and are intended to be cooked prior to consumption.

"Traditional" ActiveTech™

The ActiveTech™ modified atmosphere system, in commercial use in the United States since 1998, is a modified atmosphere system for packaging fresh cuts of muscle meat, or portions of ground meat. AT2001 is a refinement of ActiveTech™, and differs from it only in the addition of 0.4% CO to the modified atmosphere.

In the "traditional" ActiveTech™ system, the meats are placed in polystyrene trays and covered with oxygen-permeable, flexible polyvinyl chloride ("PVC") overwraps. The wrapped trays of meat are then placed within an outer barrier bag from which ambient air is removed and replaced with a blend of 30% carbon dioxide (CO_2) and 70% nitrogen (N_2). An activated oxygen-absorbing sachet is also added within the outer bag.

This modified atmosphere maintains the packaged meat in an oxygen-free deoxymyoglobin state, with its distinctive purplish appearance that is generally considered undesirable by consumers. The traditional ActiveTech™ system relies on the rapid reduction of the oxygen content of the outer bag. Once the oxygen is removed, a "seasoning" phase begins during which enzymatic effects take place so that the meat will be able to "re-bloom" when once again in the presence of oxygen. As the residual oxygen in the package is consumed by the activated oxygen scavenger, red meat oxymyoglobin is first subject to rapid conversion to metmyoglobin (brown) at very low partial pressures of oxygen, e.g. 0.5% oxygen. This low partial pressure region of oxygen is necessarily passed through prior to ultimately reaching 0% in the package and the conversion to deoxymyoglobin (purple). This seasoning phase can take up to 5 days.

Before display to consumers at retail, the outer bag, and thus the modified atmosphere, is removed, and the traditionally wrapped product (in polystyrene foam tray with PVC overwrap) is permitted to "re-bloom" to its familiar appearance through creation of oxymyoglobin on the meat's surface.

AT2001

In the AT2001 modified atmosphere system, as with traditional ActiveTech™, fresh cuts of muscle meat, or portions of ground meat, are placed in polystyrene trays and covered with oxygen permeable flexible PVC overwraps. The wrapped trays are placed within the outer barrier bag, the air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide (CO_2) and the balance nitrogen (N_2). As with the traditional AT system, an activated oxygen-absorbing sachet is added within the outer bag to create and maintain an oxygen-free environment for the packaged meat during storage.

As noted, meat packaged in traditional ActiveTech™ undergoes a myoglobin pigment conversion from oxymyoglobin (red) to metmyoglobin (brown) to deoxymyoglobin (purple) in the oxygen free environment. The metmyoglobin formed generally will convert to deoxymyoglobin in the oxygen free storage environment in about 5 days, a period of time referred to as the "seasoning period". However, the meat's ability to convert all of the metmyoglobin formed to deoxymyoglobin during the seasoning period and then fully rebloom to oxymyoglobin upon re-exposure to normal, oxygen-rich atmosphere at retail, is a function of a multitude of unpredictable, uncontrollable factors in the meat such as age, muscle

location, and enzyme energy level. This is a key weakness of all current low oxygen packaging systems.

Meat packaged in the AT2001 atmosphere will instead convert from oxymyoglobin to carboxymyoglobin (red) in the package due to the inclusion of 0.4% CO in the modified atmosphere. This conversion occurs during the initial 24 hours as the free oxygen in the headspace is consumed. Thus, the CO effectively protects the myoglobin from converting to metmyoglobin as the oxygen in the package is removed. This feature is especially important for the most pigment sensitive meats such as those from the round. The meat will continue to maintain its red color while in storage until the package is opened for retail display, when the outer bag (and modified atmosphere) is removed. Since carboxymyoglobin and oxymyoglobin are essentially the same colors, no seasoning period is necessary. The meat can be opened for retail display the day following packaging.

Once in retail display, the meat's myoglobin will begin the rather slow, natural conversion to metmyoglobin (brown), akin to that seen with untreated meat, allowing for a conventional retail display life of 3 to 4 days, closer to consumers' expectations of color than results from use of high

oxygen packaging systems. Attachment 2 consists of photographs depicting the ActiveTech™ and AT2001 systems.

The AT2001 formulation will assure that the meat will have the familiar color during and following storage, eliminating the seasoning period, allowing for placement in retail display beginning at 1 day, and up to 30-40 days, after packing. For cuts of meat from the round, and other color sensitive cuts, the AT2001 will help them have a more uniform red color for retail display.

In AT2001 (as in traditional ActiveTech™), the trays and films utilized are made from familiar, FDA-approved polymers that are used in accordance with their existing approvals or GRAS status. The activated oxygen-absorbing sachet inserted into the outer bag to absorb oxygen does not contact food and is not expected to become a component of the food. Therefore, it is not a food additive under the definition in 21 USC Sec. 321(s). As an added assurance of safety, each of the sachet's components has some GRAS status or food-related approvals.

Thus, the AT2001 system adds a refinement to the existing ActiveTech™ system that will allow its utilization with whole and ground meat products that meet the processors' desire to get to market as soon as the day following processing.

d. Basis of GRAS determination: Scientific procedures

CO safety

Pactiv believes its proposed use of CO is GRAS based on scientific procedures within the meaning of 21 U.S.C. Sec. 201(s) and FDA's implementing regulations in 21 CFR Sec. 170.30 and including FDA's proposed rule published on April 17, 1997 (62 FR 18937).

CO is a colorless, odorless gas that is poisonous to humans if inhaled at much higher levels than are involved with the use that is the subject of this Notice. It is formed when carbon is not completely burned, for example, in the combustion of fuels.

It is well known that CO creates negative health effects at elevated levels because it out-competes oxygen for attachment to the hemoglobin molecule. The resulting carboxyhemoglobin levels in the blood are associated with severe health effects. In addition, the equilibrium rate for the exchange of carboxyhemoglobin for oxyhemoglobin is very slow, and the resulting level of carboxyhemoglobin is a function of the CO level in the respired air, the time of exposure and the level of activity of the individual. Typical atmospheric CO levels are <20 mg/m^3 as an 8 hour mean (higher in

urban and high traffic areas), and typical carboxyhemoglobin levels due to natural background CO range between 1.2 and 1.5%.

CO is recognized as a significant air pollutant at higher levels. Automobile exhausts, industrial processes and boilers and incinerators all contribute to air quantities of CO. According to the U.S. EPA Office of Air and Radiation:

> Carbon monoxide enters the blood stream and reduces oxygen delivery to the body's organs and tissues. The health threat from exposure to CO is most serious for those who suffer from cardiovascular disease. Healthy individuals are also affected, but only at higher levels of exposure. Exposure to elevated CO levels is associated with visual impairment, reduced work capacity, reduced manual dexterity, poor learning ability, and difficulty in performing complex tasks. EPA's health-based national air quality standard for CO is 9 parts per million (ppm) [10 mg/m^3] measured as an annual second-maximum 8-hour average concentration.

"Summary regarding carbon monoxide" as part of discussions of 6 principal pollutants, U.S. EPA Office of Air and Radiation.

No health effects result when carboxyhemoglobin levels are under 4% to 5% in healthy adults. Carboxyhemoglobin levels of 2 to 3% may have negative effects on those with cardiovascular disease or other sensitivity. See, Environmental Health Criteria 13, Carbon Monoxide, World Health Organization, Geneva, Switzerland (1979), p. 15.

The US Occupational Safety and Health Administration's air contaminants regulation, 29 CFR Sec. 1910.1000, lists 50 ppm and approximately 55 mg/m^3 of CO as the 8-hour Time Weighted Average of exposure for the substance. 29 CFR Sec. 1910.1000.

By contrast, as explained below, the worst case estimated intake of CO attributable to AT2001 is 1.88 mg CO/meal.

The US FDA has not established an Acceptable Daily Intake for CO. Nevertheless, CO exposure, at levels much higher than those attributable to AT2001, for decades has been permitted within the existing FDA and USDA food additive regulatory provisions:

- Wood smoke ("smoke flavoring"), conventionally including CO as a component, is permitted by regulation as an ingredient in meat and poultry products pursuant to 9 CFR Secs. 318.7(c)(4)[meat], 381.147(c)(4)[poultry], 424.21(c).
- The specifications for Combustion product gas in 21 CFR Sec. 173.350 permit CO up to 4.5 percent by volume in such gases, which may be used in the processing and packaging of beverages and other foods except fresh meats, to remove and displace oxygen. Such gases are commonly used to package fruits and vegetables.

- In 2000, FDA responded favorably to GRAS Notice 000015 from Hawaii International Seafood, Inc. for the use of tasteless smoke, before freezing of tuna, as a preservative, specifically to preserve taste, aroma, texture and color. GRAS Notice (GRN) No. 000015, March 10, 2000. CO is a primary component of conventional smoke, which that Notice asserts is Generally Recognized As Safe based on decades of safe use in a variety of foods, which uses are recognized by FDA and incorporated into numerous food standards that permit smoking of cheeses. CO is also a primary component of tasteless smoke, along with nitrogen, oxygen, carbon dioxide and methane. The tasteless smoke is used to impart a "preservative effect." As noted in FDA's March 10, 2000 letter about the GRAS Notice, "In Hawaii International's view, tuna treated with tasteless smoke and tuna treated with conventional smoke contain comparable levels of carbon monoxide, carbon dioxide, hydrocarbons, and phenols." FDA's letter notes that it "has no questions at this time" regarding Hawaii International's conclusion that the use described is GRAS, though, in keeping with current regulatory practice, it had not made its own determination.

CO is listed as a reproductive toxicant by the State of California pursuant to its Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). California law contemplates that exposures to listed reproductive toxicants will be accompanied by a warning, unless the exposure is less than 1/1000th of an established no observable effect level. Cal. Health and Safety Code, Sec. 25249.6. No such level has been established for CO. Almost without question, though, any such future level (which will have a dubious connection to safety principles in any event, due to the design of Prop. 65), will be more than 1,000 times any possible exposure that could result from AT2001. The worst-case potential exposures from AT2001 are tiny fractions of the established occupational and environmental exposure levels (see below), which themselves are certain to be well below any level at which reproductive toxicity is ultimately is deemed to result.

Effects on Fresh Meat and Consumption

Analysis of the AT2001 system makes plain the lack of any safety issue from consumption of treated meats. Additionally, similar technologies employing CO as part of a modified atmosphere gas mixture analyzed the technologies for effects on meat in terms of microbial load and organoleptic

properties including color, and for the safety of consumption of treated meats, specifically, any tendency of the consumed meat to expose consumers to levels of carboxymyoglobin. Further important evidence is obtained from examination of the actual experience since 1985 in Norway of packaging fresh red meats in 0.3 – 0.5 % CO for retail.

Safety: Effects on carboxymyoglobin levels

Consumption of meat treated with AT2001 is not expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat.

An Estimated Daily Intake ("EDI") of CO attributable to the AT2001 use can be calculated as follows. First, we assume the following reasonable values for the exposure parameters:

(1) An AT2001 bag contains 1.5 L modified atmosphere with a CO concentration of 0.4%, that is equivalent to approximately 0.006 L of CO in the bag (= 6 mL CO).

(2) At 28 g CO per mole and approximately 22.4 L per mole, the mass of CO per unit volume may be calculated: (28 g/mol)/(22.4 L/mol) = 1.25 g/L = 1.25 mg/mL.

(3) The AT2001 bag contains 2 lbs (approximately 1.0 kg) of ground meat.

(4) Approximately 30% of the total amount of CO is absorbed into the meat (based on Watts, D.A.; Wolfe, S.K.; Brown, W.D., "Fate of [^{14}C] Carbon Monoxide in Cooked or Store Ground Beef Samples", J. Agric. Food Chem., Vol. 26, No. 1 (1978), pp. 210-214). Therefore, the amount of CO taken up by the meat is [(0.3)*(6 mL/bag)*(1.25 mg/mL)] / [1.0 kg meat/bag] = 2.25 mg CO / kg meat.

(5) If we assume that a person consumes an 8.8 oz steak (250 g = 0.25 kg meat), or ground equivalent, at a single meal[2], that 85% reduction in CO content occurs during cooking, and that 100% of the ingested CO is absorbed, then the maximum amount of CO exposure is (0.15)*(2.2.5 mg CO /kg meat)*(0.25 kg meat/meal) = 0.084 mg CO/meal.

Next, comparison may be made of the of the consumer EDI for CO to that amount inhaled during an 8-hour period at the EPA's National Ambient Air Quality Standard ("NAAQS") level. 40 CFR Sec. 50.8, National primary ambient air quality standards for carbon monoxide:

[2] Note that this is a conservative assumption. The EDI of beef for the 90th percentile intake per user is 139.2 g/d based on the most recent USDA national survey of food intake by individuals. Pactiv chose to use a larger value for beef consumption to simulate a typical to above-average consumption incident rather than an average over all meats.

The calculated, worst case consumer EDI for CO may be compared to that amount inhaled during an 8-hour period at the American Conference of Governmental Industrial Hygienists ("ACGIH") Threshold Limit Value ("TLV"). Documentation of the Threshold Limit Values and Biological Exposure Indices, p. 23, ACGIH, 1330 Kemper Meadow Drive, Cincinnati, Ohio.

(1) The ACGIH TLV is 25 ppm CO is equivalent to approximately 28.9 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows:

$$(28.9 \text{ mg/m}^3)*(5 \text{ m}^3\text{/8-hr}) = 145 \text{ mg CO / 8-hr.}$$

Thus, the ingestion of residual CO from the cooked meat is merely 1.3% of the exposure level at ACGIH TLV ((1.88 mg) / (145 mg) = 0.013 = 1.3%)

Finally, the calculated worst case consumer EDI for CO may be compared to that amount inhaled during an 8-hour period at the OSHA PEL:

(1) The OSHA PEL is 50 ppm CO is equivalent to approximately 58 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows:

$$(58\ mg/m^3)^*(5\ m^3/8\text{-}hr) = 290\ mg\ CO / 8\text{-}hr.$$

Thus, the ingestion of residual CO from the cooked meat is 0.65% of the exposure level at OSHA PEL. ((1.88 mg) / (290 mg) = 0.0065 = 0.65%).

Thus, the consumer EDI of CO from a eating meat packaged in the Active Tech 2001 bag is a small fraction of any of the currently allowed exposures by authoritative agencies. As these various limits were established to protect individual safety and health, it is plain that the worst case exposures that may result from AT2001 present no safety concerns whatsoever.

In the 1997 study, "Technological, hygienic and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat" Trends in Food Science and Technology, September 1997 [Vol. 8], pp. 307-312, Sørheim, et al. concluded that meat packaged and displayed in an atmosphere combining 60 to 70% carbon dioxide, 30 to 40% nitrogen, and less than 0.5% CO "will result in only negligible levels of carboxyhemoglobin in the blood."

The authors note that there was sparse information in published literature on exposure to CO after consumption of meat treated with CO gas. They note that "the inhalation of air containing CO at a level of 55 mg per m^3 (the acceptable level in working environments in the USA) would provide a COHb level for a prolonged time period (hours) of at least 14 times that of the level reached temporarily on the consumption of 225 g of meat that has been packaged in CO at the saturation level for myoglobin." That estimate assumed saturation of meat myoglobin and hemoglobin was maximal and the transfer of CO from the gastrointestinal tract to the blood was 100%. Sørheim, et al. (1997), p. 310. The authors concluded, "Consequently, even for such a "worst case" scenario, the treatment of meat with CO gas appears to contribute very little to COHb levels, relative to levels that are considered safe in the working environment." Sørheim, et al. (1997), p. 310.

The authors report that "CO is lost from previously CO-treated meat during storage in the absence of CO, with a half life of ~3d." Sørheim, et al. (1997), p. 310. As these fresh meats are to be cooked before consumption, CO lost during cooking is also relevant. The authors report that "When the beef was cooked at 195° C, only 0.1 mg of CO remained

per kg of meat. The loss of CO amounted to ~85%." Sorheim, et al. (1997), p. 310.

The authors also compared CO exposure from the air and estimated exposure from CO-treated meat. Their comparative table is shown below.

Table 5. Theoretical Uptake of Carbon Monoxide (CO) in Blood

Exposure method	**CO intake in 1 h**	**CO intake in 8 h**
Lungs ($15 m^3$)	24 mg x 0.625 = 15.1 mg	9.2 mg x 5 = 46.0 mg
Meat (250 g CO treated)	0.025 mg	0.025 mg

Sørheim, et al. (1997), p. 311, Table 5.

Part of the authors' analysis was the premise that absorption of CO from the gastrointestinal tract into blood will in all probability be less effective than absorption from the lungs. The authors summarized the comparison as follows:

> In order to prevent a maximum COHb level in the blood of 1.5% being exceeded, the CO concentration in air for a 1h period of moderate physical activity should not exceed 24 mg/m^3, or 9.2 mg/m^3 in 8h (according to Table 4). In contrast, the consumption of meat that had been treated for 3d in an atmosphere containing 1% CO yielded ~0.1 mg of CO per kg of meat on storage and cooking.

Sørheim, et al. (1997), p. 310, citing Watts, D.A.; Wolfe, S.K.; Brown, W.D., "Fate of [^{14}C]Carbon Monoxide in Cooked or Stored Ground Beef Samples", *J. Agric. Food Chem.*, Vol 26, No. 1 (1978), pp. 210-214.

The authors calculate that CO intake in 1h through the lungs taking in 15m^3 per day would result in 15.1 mg of CO, as compared with 0.025 mg of CO from intake of 250 g of CO treated meat. In 8 hours, the authors say the lungs will take in 46.0 mg, and the figure for meat would still be 0.025 mg. As the authors conclude,

> Estimates detailed above indicate that, even assuming an improbable 100% absorption of CO from the gastrointestinal tract into the blood, the consumption of meat that has been treated with 1% CO will result in COHb levels that are negligible (approximately 3 orders of magnitude lower) compared with those resulting from exposure in the working environment to CO at an acceptable level. Consequently, it is highly improbable that CO exposure from meat packaged in an atmosphere containing up to 0.5% will represent a toxic threat to consumers through the formation of COHb.

Sørheim, et al. (1997), p. 310.

In another published report, the storage life and characteristics of meats packaged in a modified atmosphere including 0.4% CO were studied, but under circumstances distinguishable from AT2001. Sørheim O; Nissen, H; Nesbakken, T, "The Storage Life of Beef and Pork Packaged in an Atmosphere With Low Carbon Monoxide and High Carbon Dioxide", 52 Meat Science 157-164 (1999). In the study, the meats were packed in

modified atmosphere into retail-ready packages. This study examined off odor and microflora, as well as color, comparing the 0.4% CO/ 60% CO_2 /40% N2 gas mixture with a gas mixture of 70% oxygen and 30% CO_2.

Among the points made by these authors was that there is sometimes an objection raised against using CO in retail ready meats because "the colour stability can exceed the microbiological shelf life, with the risk of masking spoilage of the meat." Sørheim, et al. (1999), p. 163. (Citing Kropf, D.H. (1980), "Effects of retail display conditions on meat colour", *Proceedings of the Reciprocal Meat Conference, 33, pp. 15-32.*) The authors assert that in those circumstances, consumers would need to rely on off odors to evaluate microbiological conditions of meat. In addition, they caution, "When a MA with CO is applied commercially, it is important to have a proper control of hygienic condition of the meat raw materials and the chill chain temperatures." See Sørheim, et al. (1999), p. 163.

AT2001, by contrast, presents no such similar problems or needs for caution. AT2001 does not mask spoilage of the meat. AT2001 does not involve use of a modified atmosphere including CO in the retail package. Moreover, as noted below, Pactiv's own commissioned experimentation with AT2001 demonstrates that AT2001 retail packages will deteriorate in color beginning almost immediately after removal of the modified

atmosphere, and that microbial load will not reach unsafe levels while the color of AT2001 meat is still acceptable to the consumer.

Safety: The Norwegian experience

In Norway, CO has been used to package fresh meats, even at retail, since 1985, with commercially satisfactory and safe results.

The 2000 submission by the Norwegian Meat Cooperative and Norwegian Independent Meat Association to the EU Commission seeking Europe-wide approval of the use of CO, "Application For Assessment Of The Food Additive Carbon Monoxide (CO) Prior To Its Authorization", is Attachment 3. The evaluation undertakes a detailed analysis of the CO exposure expected through the described packaging use. See section entitled "IV. Report by Tore Aune: "Fresh Meat in Consumer Packaging-A Toxicological Evaluation of the Use of Up to 0.5% CO in a Gas Mixture".

As the Norwegian risk assessment analysis concludes, assuming a worst-case exposure of 0.1 mg/kg from consumption of 250 grams of heated CO-treated meat, CO intake can be expected to be 0.025 mg in 1 hour or even after 8 hours. Attachment 3, p. 000154. The cited study, Sørheim, et al. (1997), utilized meat that had been treated with 1% CO. According to the authors, to stay under maximum blood levels of carboxyhemoglobin of 1.5%, "the CO concentration in the air must be 24

milligrams per mg/m^3 for 1 hour at moderate physical activity at 9.2 mg/m^3 for 8 hours...." Attachment 3, p. 000154. Assuming an adult inhales 15 m^3 per 24 hours, this translates to 15.1 mg of CO taken in 1 hour, or 46.0 mg of CO taken in 8 hours. This is in dramatic contrast to the miniscule amount expected to be ingested through meat. The Norwegian authors conclude, "From a health perspective, the use of CO in concentrations below 0.5-1% for fresh meat thus represents no toxicological risk." Attachment 3, p. 000155.

Safety: Exposure in environment

As a basis for comparison, the possible effect on ambient CO concentration associated with the release from a typical AT2001 barrier bag was estimated. A typical AT2001 barrier bag contains approximately 1.5 liters of modified atmosphere with a CO concentration of 0.4 percent, which is equivalent to approximately 0.006 liters of CO within the bag. On a mass basis, this volume of CO is equivalent to approximately 0.0075 g (7.5 mg) CO per bag.

Consider the possible use of the bag for storage of meat prior to retail display (e.g., at a supermarket). Any unassociated CO within the bag, it can be assumed, would be released to the meat processing area when the bag is opened, resulting in possible exposure by the employee(s) to the

released CO. The extent of such exposure is dependent on several factors, including the size of the meat processing area, air-mixing within the area and between adjacent areas, the number of bags opened, and the amount of free CO unassociated with the meat in the package. For these calculations, it has been conservatively assumed that none of the CO has become associated with the meat and is therefore all free to the ambient atmosphere upon opening of the package.

Assume, however, that the air volume within a meat processing area may reasonably range from 150 m^3 to 1,500 m^3, which would represent several hundred to several thousand square feet of processing area. If each bag introduces 7.5 mg CO to the air within the processing area, the corresponding concentration of CO in air would be in the range of 0.005 mg/m^3 to 0.05 mg/m^3, assuming conservatively that there is no air exchange between the processing area and other rooms or the outdoors. Thus, to exceed the occupational safety standard (i.e., threshold limit value, or TLV) of 25 ppm (29 mg/m^3), 580 to 5,800 1.5 liter bags would need to be opened within an 8-hour period. As noted above, this assumes no mixing with other areas of the building or with outdoor air.

Thus, applying the reasonable assumption that the air volume within the processing area will be exchanged with external air once per hour,

opening of 580 to 5,800 bags per hour would be required to exceed the TLV, or 4,600 to 46,000 bags per work day. The number of bags opened within a given processing area will be a function of the size of the processing area, to a given extent, but is unlikely to even approach the number of bags required to result in air concentrations at the TLV. Actual concentrations in the work area of a secondary processing facility would likely be one to two orders of magnitude below the standard. Thus, opening of bags within a work area will not alter significantly the environmental exposure to CO.[3]

Regardless, the opening of the bags does not alter significantly the environmental exposure to CO. This action qualifies for a categorical exclusion from preparation of an environmental assessment pursuant to 21 CFR Sec. 25.32 (i), which provides an exemption for, in pertinent part, "Approval of a ...GRAS affirmation petition...." 21 CFR Sec. 25.32(i). The regulation makes no specific mention of the GRAS Notice procedure, but similar treatment is warranted for a GRAS Notice. (We also note that CO as used here also qualifies for exclusion under 21 CFR Sec. 25.32(r), as CO "occurs naturally in the environment" and the noticed use "does not alter significantly the concentration or distribution of the substance, its

[3] As an aside, there is no reason to expect any difficulty achieving compliance with the OSHA Threshold

metabolites, or degradation products in the environment." 21 CFR Sec. 25.32(r).)

Corroborative information about AT2001

The specific AT2001 system has been thoroughly tested to confirm that it results in the expected limited exposures to CO, and has no adverse effects on the treated meats. A study of meats treated with AT2001 commissioned by Pactiv examined its effects on initial product color, stability of color during display, and the central safety consideration of the relationships between color deterioration and microbial populations.

The study, conducted by faculty of the Department of Animal Sciences & Industry of Kansas State University, Manhattan, Kansas, examined steaks from three cuts of beef (strip loin, tenderloin, and inside round steaks), as well as ground beef. The study report is Attachment 4. The meats were packaged in AT2001 atmosphere, then stored at 35° F or 43° F for up to 35 days. Cuts were then placed under simulated retail conditions by being removed from the AT outer package and displayed at 34° F until their color approached consumer unacceptability. Comparisons

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Limit Value at plants using the AT2000 technology to fill bags. Experimental use of an exhaust hood over the machinery has resulted in no measurable increase in CO ppm levels near the line.

were made to similar products that had been exposed to oxygen but not CO.

Among the study's conclusions were:

(1) Color: AT2001 *system resulted in products that were equally red to products packaged with traditional oxygen permeable overwrap.* When the AT2001 outer bag was removed, the product's conversion to oxymyoglobin occur red in 60-90 minutes and then had a typical bright red color. Visual appearance was improved, especially in the tenderloin and inner part of the inside round steaks, throughout display. Color deterioration compared well to baseline products exposed to oxygen. For tenderloin and inside round steaks, and to a lesser degree for ground beef, display time was increased only slightly in the AT2001 samples.

(2) Bacterial growth: Bacterial growth was neither encouraged nor suppressed by the addition of CO to the ActiveTech™ *gas blend (nitrogen and carbon dioxide)*, although microbial growth curves changed in slope and exponential growth according to the environment in the packages. Aerobic bacteria and facultative anaerobes followed typical patterns of growth according to environmental conditions.

(3) Spoilage indicators: CO neither masked spoilage, nor extended color life beyond the point of wholesomeness (i.e., the point of microbial soundness).

A summary of the study follows.

A random selection of all steaks and ground beef packaged using oxygen-permeable polyvinyl chloride ("PVC") film were placed in display to serve as a baseline for color and microbiological comparisons. Products were expected to have the lowest microbiological load and ideal color stability using traditional packaging and display conditions for products exposed only to atmospheric oxygen. The inherent muscle chemistry responsible for good color life also was optimal. If the product exposed to CO were to have extended meat color life, then it will be compared to the baseline "control" with the "best" possible color.

To measure color changes, visual scores were considered the "standard" with instrumental color being discussed relative to its agreement or disagreement with the visual panel, ie, did the objective measurements confirm what the color panel saw? Visual scores of ≥ 3.5 were considered borderline acceptable. When samples reached this discoloration, they were removed from display. Normally, a* values (higher values indicate more redness) are highly correlated to visual appraisal.

Inside round steaks typically are two-toned in color. The inner portion (ISM) is much less color stable than the outer portion (OSM). These portions were scored separately since one portion may have acceptable color while the other has unacceptable color that would be discriminated against by consumers resulting in the whole cut being judged unacceptable in color. The effects of CO on this bi-colored muscle were needed to confirm that color was not excessively extended in either portion.

Average fat and moisture contents of the ground beef were 19.5 and 61.6%, respectively. The pH of both intact muscles and the ground beef ranged from 5.3 to 5.7. The initial aerobic plate counts and lactic bacteria counts for all products were relatively low and indicative of good microbial quality of the raw materials and good sanitation. Furthermore, coliforms and *E. coli* were below the detection limit throughout the study.

The color of ground beef and steaks entering display (after MAP storage at 2 temperatures) was an attractive, typical red color. Although there were several significant differences in visual scores and a* values (Attachment 9, Table 2 and Figures 1-10 at day 0) for product CO vs. baseline cuts, the variation in color was usually within ± 0.5 of a color score.

Color results: In general, the initial color of product exposed to CO was very similar to the color of steaks from the baseline display (never exposed to CO). When differences occurred, they were more related to either storage temperature or postmortem age of the product.

Panelists did not consider the color of product exposed to CO atypical. Cuts exposed to CO generally appeared more uniformly bright-red and would be expected to have high consumer appeal. These results were expected, as CO is known to preferentially form a ligand with the colored pigment (myoglobin) in meat resulting in a more intense red pigment known as carboxymyoglobin.

In the AT2001 system, Pactiv uses a low level of 0.4% CO, and obtains a red color very similar to the normal red oxymyoglobin pigment of fresh meats exposed to oxygen.

Color stability results: A critical next question was whether the carboxymyoglobin formed on the surface was more stable than the oxymyoglobin formed in baseline product. Further, did the carboxymyoglobin deteriorate in a predictable way that consumers could continue to use visual color to judge freshness or potential spoilage?

Product exposed to CO during MAP storage had color deterioration during display. (See visual panel scores (Attachment 4, Figures 1-5) and

instrumental color (a* values, Attachment 4, Figures 6-10).) As expected, visual scores increased (color deteriorated) and a* values decreased (loss of redness) as days in display increased. In several instances, color appeared to improve late in display – as indicated by a decrease in visual scores (see ground beef, strips loins and tenderloins at 43°F). These decreases were not a return of redness, but resulted from removal of discolored packages the preceding period, leaving product with less overall discoloration remaining in the case.

In general, the color deterioration profiles followed an expected pattern. Namely, the freshest product (baseline packages) had the most stable, red color and the most days in display needed to reach borderline discoloration of all treatments. (Attachment 4, Table 3 scores to 3.5) Exceptions occurred for the inside portion of the inside round and tenderloin products, where the product exposed to CO had slightly more stable color than the baseline product (Attachment 4, Table 3). These two muscle areas are well known by retailers as having short color life. Thus, CO appeared to improve color life when the inherent muscle chemistry desired for color was limited.

For product from MAP, the longer the storage time, the faster the deterioration, especially at the higher storage temperature (Attachment 4,

Tables 2 and 3). For packages stored at 43°F, which was a mildly abusive temperature, color deterioration would be expected to accelerate. This phenomenon also is illustrated in Attachment 4, Figures 1-10.

There was no evidence the color shelf life was unexpectedly lengthened by exposure of meat to CO in MAP. Changes in a* values (and other instrumental measures of color not shown) followed the same pattern of color deterioration observed by the visual panelists.

Color and microbial data: Initial, pre-display microbiological data suggested that the raw materials were fresh and processed using good hygienic practices. For intact cuts, lactic acid bacteria, generic *E. coli*, and total coliform counts were below the detection limit of 1.76 colony forming units (CFU)/in^2. Initial, pre-display aerobic plate counts ("APC") for intact muscles ranged from 1 to 1.63 $\log_{10}$ CFU/in^2 . Post-display counts were higher ($P<0.05$) than pre-display APC which was an increase in bacterial proliferation and typical deterioration. However, all product had sufficient microbes to be susceptible to spoilage.

Baseline products were pulled from display when the visual panel scores reached ≥ 3.5. However, the APC did not exceed 5 $\log_{10}$ CFU/unit as shown in Attachment 4, Figures 15-18. Furthermore, off-odor scores for

product at end of display (Attachment 4, Table 3) ranged from no to slight off odor.

Thus, color life in this base population did not exceed microbial soundness, which is generally accepted as < 100 million CFU/g hamburger (<1 x 10^8). (Principles of Meat Science, 3d Ed., Hedrick, H.B.; Aberle, ED, Forrest, JD; Judge, MD; Merkel, RA, Eds, Kendall/Hunt Publishing Co., Dubuque, Iowa.

Similar trends in microbial growth occurred in post-displayed samples stored in MAP compared to baseline products. Microbial patterns for product deterioration are shown in Attachment 4, Table 4 and Figures 11-18. Products stored under MAP at a slightly abusive temperature showed, as expected, a more rapid increase ($P<0.05$) in microbial counts compared to samples stored at 35°F. For post-MAP (pre-display) and post-display samples, APC were higher at 45°F than 35°F (Table 4), and during the later days of storage at the higher temperature, differences were more obvious. Significant changes ($P<0.05$) occurred in all cuts and ground beef with the exception of semimembranosus muscle. Counts for the SM muscle were lower than expected and no significant changes occurring until day 35 of MAP storage. This suggests that quality products that have been handled

in a sanitary fashion can be stored in the AT2001 system up to 35 days without comprising microbial quality.

The APCs for intact strip loin and tenderloin steaks stored at 35°F were lower (P<0.05) on all days of display on days 21 and 35 post-MAP than steaks stored at 43°F (Attachment 4, Figures 12 and 14). Although products did not show a difference in APCs 7 days post-MAP, those products stored at the higher temperature (43°F) were more inferior 21 and 35 days post-MAP.

One goal of this research was to see if the color of CO-treated meat might mask spoilage. Visual color scoring was considered as the "standard" for determining the time to remove products from display. Because the visual panel scores were the deciding factor for length of shelf life, the interdependence between visual color and APC, LAB, and odor were considered quite important.

Attachment 4, Figures 19-21 show aerobic and lactic bacterial growth and odor scores at the end of display plotted against their corresponding visual color scores. All data observations were summed over storage temperature, storage time, and product type and plotted in one graph. If color masked spoilage, then there would be multiple points in the upper left

quadrant of the plot, the area represented by unacceptable microbial counts and off odors but with acceptable color (i.e., scores <3.5).

This did not occur with any frequency in any of the three plots. Thus, it does not appear that exposure of meat to CO during extended (up to 35 days at either 35° or 43°F) caused meat color to hide spoilage.

e. Statement of availability of information

Notifier has relied on published studies and generally accepted scientific data and information as the basis of its conclusions, and those of its panel of experts, about the safety and the general recognition of a modified atmosphere system for meat incorporating 0.4% CO in the gas mixture.

II. Identity of notified substance

1. Chemical name: Carbon monoxide
2. Chemical Abstracts Service: **630-08-0**
3. Composition Specifications for food-grade material: The CO employed in this system is to be of suitable purity for food contact. Specifically, this will mean a 99.99% minimum purity, as supplied by Pactiv's commercial gas supplier, Haun Welding Supply, Inc., 6481 Ridings

Road, Syracuse, NY 13206. Attachment 5. The supplier's CO meets the following specifications, and will be referred to as "commercial grade":

Component	Specification
Carbon Monoxide	99.99% min.
Oxygen	≤ 0.5 PPM
Nitrogen	≤ 10 PPM
Carbon Dioxide	≤ 20 PPM
Methane	≤ 5 PPM
Ethane	≤ 1 PPM
Propane	≤ 1 PPM
Dimethyl Ether	≤ 1 PPM
Hydrogen	≤ 1 PPM
Moisture	≤ 1 PPM

4. <u>Properties:</u>

Relative molecule mass	28.01
Critical point	−140.2 °C at 34.5 atm (3.5 MPa)
Melting point	−205.1 °C
Boiling point	−191.5 °C
Density, at 0 °C, 1 atm	1.250 g/litre
at 25 °C, 1 atm	1.145 g/litre
Specific gravity relative to air	0.967
Solubility in water at 0 °C, 1atm	3.54 ml/100 ml
at 25 °C, 1 atm	2.14 ml/100 ml
at 37 °C, 1 atm	1.83 ml/100 ml[a]
Conversion factors:	
at 0 °C, 1 atm	1 mg/m^3 = 0.800 ppm[b]
	1 ppm = 1.250 mg/m^3
at 25 °C, 1 atm	1 mg/m^3 = 0.873 ppm
	1 ppm = 1.145 mg/m^3

[a] Value obtained by graphic or calculated interpolation (Altman et al., 1971).
[b] Parts per million by volume

5. Analyses: ASTM D1946, "Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD)", may be utilized to measure the quantity of CO present in gas mixtures. A copy of the method is Attachment 6.

III. Self-limiting levels of use

Studies of modified atmospheres for packaging meat that contained both higher and lower levels of CO have established that the 0.4% used in the AT2001 system both has advantageous characteristics and avoids disadvantages seen with lower or higher levels. A CO level of 0.4% is sufficient to produce stable, cherry red color, (Sørheim, et al. (1997), and use of CO through retail display time may result in masked spoilage.

IV. Basis of GRAS determination.

Pactiv believes its use of CO is GRAS based on scientific procedures, 21 CFR Sec. 170.30(b), and convened a panel of experts qualified by scientific training and experience to evaluate the safety of food, food additives and food ingredients. The experts have reviewed and evaluated the publicly available information summarized in this GRAS Notice. Their testimonial

letters are attached as Attachments 7 through 10. The above discussion and citations to generally available accepted scientific data, information, methods and principles relied upon, together with the anticipated consumption levels for both CO and meat treated with CO, provide ample basis to conclude that the use of CO at 0.4% in a modified atmosphere for packaging fresh meats is both safe and generally recognized as such by qualified experts.

The panel consisted of the following experts, whose GRAS opinions and curricula vitae are attached as attachments 7 through 10.

1. Daren Cornforth, Ph.D.
   Professor
   Department of Nutrition and Food Sciences
   Utah State University
   750 N. 1200 E.
   Logan, Utah 84322-8700

Dr. Cornforth is a professor in Nutrition and Food Sciences at Utah State University, Logan, Utah, and received his Ph.D. in food science and human nutrition from Michigan State University. He has performed extensive research and published multiple articles on the subject of meat color.

2. Vasilios Frankos, Ph.D.
   Principal
   Environ Corp.
   4350 N. Fairfax Dr.

Suite 300
Arlington VA 22203

Dr. Frankos is a Principal at ENVIRON corporation, Arlington, Virginia, a scientific consulting firm, and has over 20 years of experience in the toxicological and pharmacological evaluation of data used to assess the risks posed by foods, food additives, and other substances. He holds a Ph. D. from the University of Maryland Pharmacy School in Pharmacology and Toxicology.

3. Melvin C. Hunt, Ph.D
Professor
Weber Hall
Dept. of Animal Sciences and Industry
Kansas State University
Manhattan, KS 65506

Dr. Hunt is a professor of food science at the Department of Animal Sciences and Industry at Kansas State University, Manhattan, Kansas. He received his Ph.D. in food science at the University of Missouri. Among his many research projects and publications are multiple studies relating to meat color and the effects of various environments on meat color.

4. Oddvin Sørheim, Ph.D.
Senior Research Technologist
MATFORSK – Norwegian Food
Research Institute
Osloveien 1

N-1430 Ås
Norway

Dr. Sørheim is a Senior Research Technologist at the Norwegian Food Research Institute, Osloveien, Norway. He received his Ph.D. in food science from the Agricultural University of Norway, and has performed extensive research and industry consultation, and published numerous articles on meat, including extensive experience with the use of CO in modified atmosphere packaging of meat.

Pactiv is not aware of any reports of investigations that are inconsistent with the GRAS determination relating to the use described.

Conclusion

Based on all the above information, Pactiv Corporation has concluded that its use of 0.4% CO within the AT2001 modified atmosphere system for packaging fresh meat is Generally Recognized as Safe within the meaning of 21 U.S.C. Sec. 321(s).

Sincerely,

Eric F. Greenberg

K-STATE
Kansas State University
Animal Sciences and Industry
K-State Research and Extension
232 Weber Hall
Manhattan, KS 66506 -0201
785-532-6533
Fax: 785-532-7059

August 8, 2001

Eric F. Greenberg
Of Counsel
Ungaretti & Harris
3500 Three First National Plaza
Chicago, IL 60602-4283

Dear Mr. Greenberg:

The purpose of this letter is to confirm that I believe the use of a small quantity of carbon monoxide in the modified packaging system know as ActiveTech (by PACTIV) is safe and should qualify as GRAS. I have been a research meat scientist for nearly 30 years and have focused most of that time on factors affecting meat color and shelf life, including packaging systems. Thus, I am familiar with most of the world literature on such systems.

Based on my review of the details of the ActiveTech 2001 modified atmosphere system employing 0.4% carbon monoxide gas in a mixture with 60 percent carbon dioxide and the remainder nitrogen, as well as the published literature and common knowledge in the field, I am confident that the use of modified atmosphere including small quantities of carbon monoxide (0.4%) to package fresh meats as used in ActiveTech 2001 system is both safe and generally recognized as safe.

Sincerely,

Melvin C. Hunt

Melvin C. Hunt
Professor

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01106USC1

SECOND DECLARATION OF GARY R. DELDUCA UNDER 37 C.F.R. § 1.132

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

October 14, 2004 Adrienne White
Date Adrienne White

Dear Commissioner:

I, Gary R. DelDuca, declare that:

1. I hold a degree of B.S. in Mechanical Engineering from Rochester Institute of Technology in Rochester, New York that was obtained in 1980.

2. From 1980-1995, I worked as a developmental and senior engineer for Mobil Chemical Company, Plastics Division. As a developmental engineer, I worked in process and product development in the area of foam products. As a senior engineer, some of my responsibilities included designing specialized machinery that included machinery directed to stacking trays for meat processes. Mobil Chemical Company, Plastics Division was purchased by Tenneco, Inc. in 1995. From 1995 to the present, I have been a Technical Manager for Tenneco

Packaging, Inc. in the area of modified atmosphere packaging (MAP) for meats. My responsibilities have included designing, developing, and implementing such modified atmosphere packaging for meat and processes using the same. In 1999, Tenneco Packaging, Inc. was renamed Pactiv Corporation ("Pactiv").

3. I am a co-inventor of the present application that is directed to methods of manufacturing a modified atmosphere packaging and modified atmosphere packaging. I am familiar with the claims in the present application.

4. After about 40 years of not allowing CO to be used with fresh meats in the United States, the Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of "fixing" the meat color, which can mask the spoilage or extend the life beyond the point of microbial soundness. The problem of fixing color using CO is known to those skilled in the art. One example of a reference that recognizes this problem is an article entitled "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon monoxide" to Sorheim, Nissen and Nesbakken. This article was discussed in the Office Action dated May 7, 2003 in the present application.

5. One example of a meat packaging system using CO in a modified atmosphere that avoided the fixing of the meat color was Pactiv's improved ActiveTech® meat packaging system. Pactiv's improved ActiveTech® meat packaging system includes meats being placed in polystyrene trays and covered with oxygen-permeable, polyvinyl chloride ("PVC") overwraps. The wrapped trays of meat are then placed in an outer barrier bag. Ambient air is removed and replaced with a blend of 0.4 vol.% carbon monoxide (CO), 30 vol.% carbon dioxide, and the balance being nitrogen.

6. The FDA stated that it had no questions regarding Pactiv's conclusion about Pactiv's improved ActiveTech® meat packaging system using 0.4% CO being GRAS because of the evidence presented by Pactiv in its GRAS notice. *See* Exhibit A. This FDA review allows Pactiv to use CO with fresh meat in its application. It is believed to be the first system to overcome the prohibition of CO with fresh meat in the U.S. in the last 40 years. Thus, an important advancement in the art of meat packaging systems was accomplished by the use of Pactiv's improved ActiveTech® meat packaging system.

7. Besides Pactiv's improved ActiveTech® meat packaging system, the Applicants invented other novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoid the concerns of "fixing" the meat color. Some of these other novel approaches include low oxygen environment, meat packaging systems having (a) a first layer being a substantially permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture including 0.4 vol.% CO.

8. An example of a low oxygen environment, meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a "peelable" system. A peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. The first layer is located closest to the meat, while the second layer is located farthest from the meat. The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the substantially permeable first layer.

9. It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap).

10. The process of manufacturing the above-described peelable system is an example of a process that would be covered by independent claims 38, 119 and 138 of the present application. The above-described peelable system is an example of modified atmosphere packaging that would be covered by independent claims 76 and 157 of the present application.

11. One company that makes such a peelable system using 0.4 vol.% CO is Cryovac, which is marketed under the name Darfresh®. Cryovac's Darfresh® meat packaging system includes two layers – a first layer being a permeable layer and a second layer being an impermeable layer. The second layer is adapted to be removed at the point of sale by a tab so as to allow CO to escape from the package. The atmosphere within the package equilibrates with the standard atmosphere outside the package.

12. In a GRAS (Generally Recognized as Safe) notice to the FDA, Cryovac represented that this change in the atmosphere within the Cryovac package by removing the second layer "allow[s] the meat pigment color to change over time as though it has not been exposed to CO. As a result, the "FDA concluded that Cryovac's MAP system fell within the scope of GRAS Notice No. GRN 00083 [which is directed to the above-discussed Pactiv's improved ActiveTech® meat packaging system] ." Exhibit B. Thus, both Cryovac and the FDA believe that such a peelable system using 0.4 vol.% CO does not fix the color of the meat pigment to red.

13. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: October 14, 2004

Gary R DelDuca

Gary R. DelDuca

United States Department of Agriculture
Food Safety and Inspection Service
Office of Policy, Program Development and Evaluation
Washington, D.C. 20250/3700

Mr. Eric F. Greenberg
3500 Three First National Plaza
Chicago, IL 60602-4283

MAY 10 2002

Dear Mr. Greenberg:

I am responding to your letter of April 12, 2002, regarding the Generally Recognized as Safe (GRAS) Notice, GRN 000083, for the use of carbon monoxide (CO) as part of a modified atmosphere packaging (MAP) system which is produced by the Pactiv Corporation.

It is our understanding that there are no Food and Drug Administration (FDA) regulations that classify CO as a safe or suitable ingredient for use in foods. CO may be part of a substance called "combustion product gas" (21 CFR 173.350) and may not exceed 4.5 percent of the combustion gas by volume. The use of combustion gas is as a packing medium for various foods, with the specific exception of fresh meats.

FDA's GRAS Notice No. GRN 000083, dated February 21, 2002, stated that the FDA had no questions at that time regarding Pactiv's conclusion that the use of CO is GRAS under the proposed conditions of use, i.e., a MAP system that uses a combination of gases (30 percent carbon dioxide, 69.6 percent nitrogen, and 0.4 percent CO). In this system, the meat cut is put on a tray which is put in a hermetically sealed permeable film that is then placed in a pillow pack into which the gases are flushed. The meat cut is not directly treated with CO which is among the gases in the outer packaging. Once the outer packaging is removed at retail, the meat pigment color changes as it would normally, i.e., the shelf-life is comparable to meat that has not been shipped in the Pactiv system. Thus, the Food Safety and Inspection Service (FSIS) concluded that the use of CO in the modified atmosphere packaging system (ActiveTech™ 2001) produced by Pactiv would be acceptable for packaging red meat cuts and ground meat.

It is important to note that GRAS Notice GRN 000083 is specific to the use of a combination of gases in the Pactiv modified atmosphere packaging system. Thus, there still is no allowance for the use of CO directly in the production of meat products.

If you have any additional questions, please contact Mr. Jeff Canavan or me at Area Code (202) 205-0279.

Sincerely,

for Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

United States Department of Agriculture
Food Safety and Inspection Service
Office of Policy, Program and Employee Development
Washington, D.C. 20250/3700

Mr. Ralph Simmons
Keller and Heckman, LLP
1001 G Street NW
Suite 500 West
Washington, DC 20001

FEB 5 2003

Dear Mr. Simmons:

I am responding to your request of December 11, 2002, on behalf of your client, Cryovac North America (Cryovac). On November 15, 2002, Cryovac requested that the Food Safety and Inspection Service (FSIS) review the acceptability of its low oxygen case ready modified atmosphere packaging (MAP) system that incorporates carbon monoxide (CO) to maintain wholesomeness. In response to the information that you and your client provided, FSIS informed Cryovac in a letter dated December 19, 2002, that FSIS would need to consult with the Food and Drug Administration (FDA) to request their interpretation on whether Cryovac's use of CO in their MAP system is consistent with GRAS Notice No. GRN 000083.

FDA responded in writing to our request on January 27, 2003, in which they conveyed that the use of CO in Cryovac's MAP system is generally recognized as safe (GRAS). Specifically, Cryovac's MAP is similar to the MAP system in GRAS Notice No. GRN 000083, i.e., the MAP uses the same concentrations of carbon dioxide, nitrogen, and CO, except that the physical packaging system is slightly different. However, because Cryovac's container has a tab that is removed at the point of sale to allow the CO to escape from the package, the atmosphere within the package can equilibrate with the standard atmosphere outside the package. This change in the atmosphere within the package will allow the meat pigment color to change over time as though it had not been exposed to CO. As a result, FDA concluded that Cryovac's MAP system fell within the scope of GRAS Notice No. GRN 000083.

Because Cryovac's use of CO in their MAP system is consistent with GRAS Notice No. GRN 000083, FSIS does not object to the use of this MAP system to package case ready fresh meat. If you have any additional questions, please contact Mr. Jeff Canavan, Food Technologist, at Area Code (202) 205.0279.

Sincerely,

Sally L Jones

Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

MEMORANDUM OF CONFERENCE

May 22, 1962

BETWEEN: Mr. Donald W. Thomas, Legal Counsel, The Whirlpool Corporation
Benton Harbor, Michigan

and

Mr. A. T. Spiher, Jr., Food Additive Petitions Control Branch

SUBJECT: Combustion product gas.
Food Additive Petition 751.

Mr. Thomas called without previous appointment to discuss the above petition. He said that he had received my letter of May 10, 1962, in which we filed the petition, and said that we may need additional data on meat. These data would be needed to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated.

I explained to Mr. Thomas the way in which petitions are handled, and explained the question which we have concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color. I said that they could either submit additional data on this point or they could request withdrawal of the portion of the petition for meat, and explained the different courses of action.

Mr. Thomas said that they had data concerning the retention of red color in meat, and they will get it together. He was concerned, however, about whether he should submit this as an amendment which would start the time clock over, or should withdraw animal products from the petition, to submit later on.

I said that this was a decision which he would have to make in the light of the explanation we had given him, and I suggested that he submit the data which they have and let us look at it before they did anything additional, because what they had done might be sufficient for our people.

I further suggested that when he submit the information for meat, he should supplement the data in the petition to explain exactly how the combustion product gas is to be used on the various commodities named in their petition. He said that he would do so. Briefly, he said that the gas was to be used as the atmosphere in a cold storage room.

In response to a question, he said that they had tested the effluent from their generator and were satisfied that the gas complied with the requirements established in the food additive regulation.

cc: FA DF DP BE DCM DFS
ATSpiher:nrg:5/25/62

Whirlpool
CORPORATION

ADMINISTRATIVE CENTER • BENTON HARBOR, MICHIGAN

July 23, 1962

Mr. Alan T. Spiher, Jr.
Food and Drug Administration
Department of Health, Education and Welfare
Washington 25, D. C.

Subject: Food Additive Petition No. 751 JA 3/9/62

Dear Mr. Spiher:

We are in receipt of your letter of May 10, 1962, advising us of the filing of Food Additive Petition No. 751 with an effective filing date of March 24, 1962.

In view of your comments in the above-mentioned letter, we now request that our petition as originally presented be amended so as to delete any reference to animal products wherein paragraph 121.1060, section (c) of Part 121, Sub-Part D of Title 21 would now read as follows:

> (c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of citrus products, vegetable fats and vegetable oils, coffee, wine, fruit and fruit products and vegetable and vegetable products.

The following comments are submitted to further supplement the Remarks section of our first letter of March 6, 1962.

In food studies conducted at the Whirlpool Research Laboratories involving the use of combustion product gas as set forth in paragraph 121.1060 of Title 21, fruits and vegetables were stored under refrigeration at temperatures between

1) A

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32° and 45° F. and in their normal distribution containers, that is, baskets, crates and boxes. Products so stored had a shelf life of from three to five times that of air-stored food held at the same temperature. The results of one such study involving apples stored in air versus apples stored in conventional controlled atmosphere versus apples stored in combustion product gas are presented in the attached table. It will be noted that apples stored in combustion product gas had firmer flesh and a lower incidence of scald than did apples stored either in air or conventional controlled atmosphere even though the apples in combustion product gas were in storage for a longer period of time.

The combustion product gas under study at Whirlpool would most likely be used in the following general areas:

1. Fresh fruit and vegetable storage

2. Processors - storage, packaging and processing

3. Transportation

Because of these diverse applications, our petition requests approval for fruit and vegetable "products" as well as the natural, original raw fruits and vegetables.

To expand on the use of combustion product gas by food processors, the following examples are presented:

1. Storage of fruits and vegetables in order to have better quality control, improve yield and extend packaging season.

2. Packaging of processed foods in inert gases, i. e., nitrogen and/or carbon dioxide to prevent oxidative changes that may develop during storage.

3. Use of gas mixtures in certain processing steps as a "blanket" to keep out oxygen and prevent the associated undesirable changes.

We are hopeful that the requested amendment to the petition as well as the supplemental information presented above will clear up any questions concerning Food Additive Petition No. 751 and that favorable action will be shortly forthcoming.

Very truly yours,

WHIRLPOOL CORPORATION

By Allen E. Mahaffay
Vice President